COVID-19, Processing, and the Importance of Definitions: Focus on Face Masks

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The COVID-19 pandemic, caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has been a challenge personally and professionally. Among the challenges is that of maintaining the supply of critical personal protective equipment (PPE), such as face masks, to those at risk.

Considering Mask Processing Activities

Single-use, disposable face masks rated as N95 have been shown to capture 95% or more of airborne particulates (measuring ≥0.3 µm in diameter) and effectively remove infectious microorganisms from the air.[1] They therefore are a critical supply when addressing a global respiratory-related pandemic. High-volume demand for disposable face masks due to COVID-19 has resulted in many healthcare facilities considering mask processing to address shortages.

Processing (or reprocessing) is defined as an "activity to prepare a new or used health care product for its intended use"[2] and can include any or a combination of processes (e.g., cleaning, disinfection, inspection, repackaging, sterilization). The masks typically are labeled as single use, and processing methods have not necessarily been designed and validated for subsequent use. As detailed in guidance issued by the Food and Drug Administration (FDA),[3] it is important to remember that mask processing activities should demonstrate effectiveness in at least four situations:

1. Inactivation of target microorganism(s)
2. No damage to mask performance
3. Appropriate fit to the wearer
4. Safe for the subsequent user

With the first of these requirements—the inactivation of a target microorganism, such as SARS-CoV-2 virus—microbiological quality terminology is routinely misused, which leads to confusion.

In microbiological quality, microorganisms are known to range in their resistance to inactivation.[4] The potential for the number and types of microorganisms, in their natural state, is taken into account during validation of the different antiseptic, disinfection, and sterilization processes used for treatment of surfaces and product. Depending on the process selected, the process may be designed and validated to kill all microorganisms (e.g., sterilization) or designed to kill specific types of microorganisms based on different levels of disinfection.

The resistance to inactivation is based on the different types of microbial structures that exist and their reactivity with the various types of antimicrobial processes used. These include the structures based on proteins, lipids, carbohydrates, and nucleic acids that make up all life.[4,5] Lipid enveloped viruses (e.g., human immunodeficiency virus, hepatitis B virus) and Gram-positive bacteria (e.g., *Staphylococcus aureus*) are among the microorganisms with greater sensitivity to these inactivation methods, while other forms (e.g., fungi, Gram-negative bacteria [nonsporulating], small nonenveloped viruses, mycobacteria, bacterial endospores) show increased resistance.

The type of microorganism of concern in COVID-19 is an enveloped virus (SARS-CoV-2). Being "enveloped" in structure informs us that it is relatively sensitive to inactivation. The outer envelope, made in part from the lipid membrane of host cells from which they are generated, is required for these viruses to infect other cells, and therefore, damage to these sensitive structures can inactivate them (rendering them unable to infect a new target cell). This is quite different from other types of nonenveloped virus (e.g., polio or parvo viruses) that are dramatically more difficult to kill.[4,6,7]

Based on this knowledge, a wide range of disinfection and sterilization processes are effective against SARS-CoV-2.[8–10] In the United States, this would include low-level disinfectants or disinfection processes, defined as being capable of inactivating

vegetative bacteria (except mycobacteria), enveloped (lipid) viruses, and fungi (but not necessarily fungal or bacterial spores).[11]

Considering the final goal of mask processing is important. Is the goal for processing to only reduce the risk of SARS-CoV-2 or are other respiratory or healthcare-associated infection risks of concern (e.g., a wider range of viruses, bacteria, fungi, mycobacteria, and bacterial spores)? With all risks in mind, the appropriate processing techniques should be used.

Key Terms: Decontamination, Disinfection, and Sterilization

A review of literature and online commentary highlight three terms used to describe mask processing: decontamination, disinfection, and sterilization. Each of these terms has a specific meaning and should be used to properly convey the level of microorganism inactivation to be expected by the processing procedure.

Decontamination

Decontamination entails removing a certain level of microorganisms and clinical soil from a used item in order to render it safe for subsequent use. However, variations can be seen in how decontamination is defined internationally and domestically. Internationally, it is defined as "a process of freeing a person or object from potentially harmful material" and can be achieved by cleaning and/or using an antimicrobial process.

In the U.S. healthcare practice setting, decontamination is defined in different ways. For example, the Occupational Safety and Health Administration (OSHA) defines the term as "the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal."[12] ANSI/AAMI ST79:2017 relates this specifically to device processing, defining decontamination as a "process of cleaning and disinfecting soiled medical devices to render them safe for handling and to the extent necessary for subsequent processing."[13]

Although the OSHA definition puts clear emphasis on the inactivation or removal of a pathogen, such as SARS-CoV-2, the ST79 definition clearly is a combination process of cleaning and disinfection. Single-use PPE, such as face masks, were not designed to be cleaned, or for residual soil (i.e., debris

Single-use personal protective equipment items, such as face masks, were not designed to be cleaned or for residual soil to be practically removed without compromising the integrity of mask performance. Therefore, use of the correct terminology—decontamination, disinfection, and sterilization—is essential to conveying the level of microorganism inactivation to be expected by the processing procedure.

typically found on a device after clinical use, such as blood, mucus, makeup) to be practically removed without compromising the integrity of mask performance. Therefore, use of the term "decontamination" to describe mask processing may be too broad and imply actions of inactivation or removal that may not be possible. For this reason, use of "disinfection" or "sterilization" is preferred, as both terms focus on the inactivation of microorganisms during the processing of masks.

Disinfection

Disinfection is used to inactivate viable microorganisms to a level previously specified as being appropriate for a defined purpose.[2] ST79 specifically defines disinfection as a process that kills pathogenic and other microorganisms by physical or chemical means.[13] Although disinfection, when applied appropriately, can inactivate most pathogenic microorganisms, some microbial forms (e.g., bacterial spores) may not be destroyed by disinfection procedures. In the United States, there are different levels of disinfection that can be defined based on expectations of microorganism resistance (as introduced above and considered in further detail below). The ultimate disinfection process is sterilization.

Sterilization

Sterilization, or a validated process used to render a product free from viable mciroorganisms,[13] provides a greater margin of safety. It is an antimicrobial process that is also dependent on having a controlled process, including sterilizer load configuration and a controlled level of microbiological quality. In the case of mask processing, the level of microorganisms and residual soil on a used mask will be unknown (as not subjected to a cleaning process). Therefore, although a sterilization process may be applied, referring to these masks as being "sterile" may not be prudent.

Conclusion

With the goal of providing a safe mask after processing, disinfection against SARS-CoV-2 is the most appropriate antimicrobial process. Since the 1950s, the Spaulding Classification has been widely used to define levels of disinfection to reduce infection risk with reusable devices/surfaces.[5] These definitions are also defined for processing by the FDA.[3,11] The levels of microbial inactivation for disinfection is characterized as being low, intermediate, or high. All of these levels of disinfection would be effective to inactivate SARS-CoV-2 according to the virus type (enveloped viruses) when used correctly. Even low-level disinfection processes, defined as killing most vegetative bacteria, some viruses (enveloped viruses), and some fungi (but not mycobacteria or bacterial spores) would be considered effective against SARS-CoV-2. Intermediate- and high-level disinfection would include activity against more resistant microorganisms, particularly mycobacteria. Therefore, approved disinfection processes could be safely used to inactivate or reduce the risk of SARS-CoV-2, if they meet the other functional requirements specified earlier.

Overall, it is important to understand the processing requirements for a device and to use the appropriate terminology to reflect the level of microorganism inactivation. This is especially critical when evaluating the processing requirements for the emergency reuse of protective masks at healthcare facilities to address a shortage of critical PPE, as appropriate definitions facilitate understanding and prevent confusion.

It is also essential to remember that in addition to the emphasis on microbial inactivation, we must ensure that face masks remain safe and effective for their intended purpose.

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